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**Hand Delivered**

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Docket Number 00N-0085; National Environmental Policy Act;  
Food Contact Substance Notification System**

On behalf of the Food, Drug, and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc. (SPI)<sup>1/</sup>, we hereby respectfully submit these comments on the above-referenced direct final rule, which was made available on May 11, 2000 (65 Fed. Reg. 30352). The direct final rule would require Environmental Assessments (EAs) to be submitted with food-contact notifications except for notifications that qualify for the same categorical exclusions currently applicable to food additive petitions and Threshold of Regulation requests.

In these comments we reiterate the Committee's position that EAs should not be required for food-contact notifications. However, these comments should not be construed by the Agency

<sup>1/</sup> The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI's 2,000 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers and raw material suppliers. The U.S. plastics industry employs 1.3 million workers and provides \$274 billion in annual shipments. Founded in 1937, SPI is the voice of the plastics industry. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with special interest and expertise in materials used in packaging for drugs, as well as foods, cosmetics, and medical devices.

00N-0085

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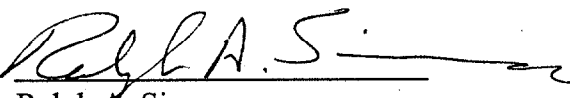
as a "significant adverse comment" to the direct final rule, and the Committee supports the rule becoming effective as scheduled.

We explained the Committee's position that environmental review of food-contact notifications is legally unnecessary in our memorandum of March 11, 1999, which was submitted to FDA at the March 12 stakeholders' meeting on the notification program, and again in comments we filed with the Agency on April 2, 1999.<sup>2/</sup> In the March 11 memorandum, we discuss the court decisions holding that federal agency procedures analogous to food-contact notification do not constitute "major federal actions," and, therefore, do not trigger the need for an EA under the National Environmental Policy Act (NEPA). In addition, the memorandum establishes that FDA clearance of a food-contact material, whether by notification or otherwise, cannot have a significant impact on the environment. The Committee continues to support the views set forth in the March 11 memorandum, but we understand that FDA is not yet prepared to eliminate environmental review of food-contact notifications. Therefore, while we reiterate our position here for the record, the Committee does not object to the direct final rule becoming effective to extend the current categorical exclusions from the need for an EA to food-contact notifications.

SPI appreciates the opportunity to comment on FDA's direct final rule. The Society would be pleased to respond to requests from the Agency for additional information pertaining to these comments.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS  
INDUSTRY, INC.

By:   
Ralph A. Simmons

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<sup>2/</sup> On April 2, 1999 we submitted comments on behalf of the Committee to Docket No. 99N-0235 in response to the notice entitled "Premarket Notification for Food Contact Substances: Public Meeting" published in the *Federal Register* on February 22, 1999 (64 Fed. Reg. 8577). This notice requested public comment on the implementation of the new premarket notification (PMN) program for food-contact substances that was authorized by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 309, Pub. L. 105-115, *amending* Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 301, 409(h) (1998)).

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